REMARKS/ARGUMENTS

Claims 1 and 4-10 are pending in the application.

Claim 1 recites a method of treating an Alzheimer's patient comprising administering a daily dosage consisting essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to the patient.

35 U.S.C. § 112

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 112(1) as allegedly failing to comply with the written description requirement. According to the Office Action, "the silence of the disclosure regarding **consisting essentially of** is not sufficient to now claim the exclusion of such steps because nowhere in the disclosure has Applicant discussed **consisting essentially of** in the context of the claimed method".

Applicants respectfully traverse this rejection. Claim 1 clearly recites that the daily dosage consists essentially of a specified amount of hypoxanthine, xanthine and/or inosine. Although Claim 1 is a method claim, the method includes administering the claimed daily dosage composition. The phrase "consisting essentially of" does not modify any "step" recited in the claim, but rather modifies the "daily dosage" by restricting its composition to the recited amounts of hypoxanthine, xanthine and/or inosine. The disclosure fully supports the claimed daily dosage composition and its administration to patients. Accordingly, withdrawal of the 35 U.S.C. § 112(1) rejection is respectfully requested.

35 U.S.C. § 103

Claims 1 and 4-10 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Laruelle et al. '387 in view of Sandyk '846 and further in view of Castillo et al. '994. According to the Office Action, Laruelle et al. '387 discloses a pharmaceutical composition suitable for increasing cerebral serotonin concentration comprising a serotonin precursor and inosine and hypoxanthine. The Examiner states that treatment consists of administering to a mammal having a lower than normal cerebral serotonin level an amount of a pharmaceutical composition as presently claimed effective to increase the cerebral serotonin level, with daily dosages to 1 to 100 mg/kg being preferred. With respect to the "consisting

essentially of" language in Claim 1, the Examiner states that such language has been treated as open-ended "comprising" language, and that it is Applicants' burden to establish that a step practiced in a prior art method is excluded from the claims. However, as noted above, Applicants' "consisting essentially of" language modifies the composition of the daily dosage that is administered to an Alzheimer's patient, rather than any "step" of the recited method.

Sandyk '846 is relied upon as teaching a method of treating neurological and mental disorders which are associated with and/or related pathogenetically to deficient serotonin neurotransmission, with Alzheimer's disease being a disorder associated with deficient levels of serotonin.

Castillo et al. '994 is relied upon as teaching herbal compositions for intervention in Alzheimer's disease which may optionally include antioxidants.

It is submitted that the present invention, as recited in Claim 1, is patentable over the prior art of record.

Laruelle et al. '387 discloses pharmaceutical compositions based upon 5-hydroxytryptophan (5-HTP) and derivatives of 5-hydroxytryptophan, in combination with a nitrogenous heterocyclic compound selected from a group that includes inosine and hypoxanthine (see abstract and column 1, line 60 to column 2, line 16). According to Laruelle et al. '387, the combination of 5-HTP and derivatives of purine, pyrimidine or pyridine bases provide novel pharmaceutical compositions capable of correcting deficiencies of serotonin metabolism:

> The present invention provides novel pharmaceutical compositions capable of correcting the deficiencies of serotonin metabolism which are characterized in that they comprise an association of 5-HTP or a derivative thereof with derivatives of purine, pyrimidine, or pyridine bases, or with a combination of derivatives of these bases.
>
> The applicants have in fact observed that the combination of 5-HTP with a purine, pyridine, or pyrimidine heterocyclic base enables the cerebral levels of 5-HTP, serotonin and 5-hydroxyindolacetic acid (5-HIAA), which is the principal metabolite of serotonin, to be considerably increased. (column 3, lines 17-29; emphasis added)

The disclosed pharmaceutical composition must have at least 5 percent 5-HTP that is chemically associated with the nitrogenous heterocyclic base (see column 3, lines 38-46). The 5-HTP-containing pharmaceutical compositions disclosed by Laruelle et al. '387 are said to triple blood levels of 5-HTP and 5-hydroxyindolacetic acid (5-HIAA), the principal metabolite of serotonin (column 4, lines 1-6). Laruelle et al. '387 discloses several specific examples of pharmaceutical compositions which were the subject of a pharmacological study. As set forth in columns 5-9, all of the studied compositions included significant amounts of 5-HTP. It is clear from the teachings of Laruelle et al. '387 that 5-HTP must be present in significant amounts in the disclosed pharmaceutical compositions, and represents a required active ingredient of the compositions that substantially affects serotonin levels when administered to patients.

In contrast, the presently claimed method excludes the use of the levels of 5-HTP taught by Laruelle et al. '387 by reciting that the daily dosage administered to the Alzheimer's patent consists essentially of from 100 mg to less than 1,000 mg of hypoxanthine, xanthine and/or inosine to a patient. The "consisting essentially of" language excludes additional ingredients that would affect the basic and novel characteristics of the claimed daily dosage. Laruelle et al. '387 teaches that 5-HTP is a required active ingredient of the disclosed pharmaceutical compositions, and must be present in order to affect serotonin levels in patients. Laruelle et al. '387 therefore establishes that 5-HTP affects the basic and novel characteristics of the disclosed composition in that 5-HTP is the active ingredient that controls the serotonin levels in patients. Those skilled in the art would recognize that the elimination of the disclosed active ingredient from the composition of Laruelle et al. '387 would materially affect the basic and novel characteristics of the composition, i.e., the control of serotonin levels. The presently claimed administration of a daily dosage that excludes the levels of 5-HTP required by Laruelle et al. '387 patentably distinguishes over the reference.

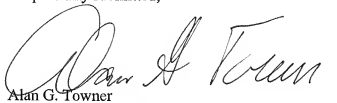
Sandyk '846 and Castillo et al. '994 do not remedy the above-noted deficiencies of Laruelle et al. '387. Even if the secondary references could properly be combined with Laruelle et al. '387 as suggested in the Office Action, such a combination would not read on the presently claimed method of treating an Alzheimer's patient by administering a daily dosage consisting essentially of the recited amounts of hypoxanthine, xanthine and/or inosine to the

patient. Accordingly, Claim 1, and Claims 4-10 which depend therefrom, are patentable over Laruelle et al. '387 alone, or in combination with Sandyk '846 and Castillo et al. '994.

In view of the foregoing amendments and remarks, it is submitted that Claims 1 and 4-10 meet the requirements of 35 U.S.C. § 112 and are patentable over the prior art of record. Accordingly, an early Notice of Allowance of this application is respectfully requested.

In the event that any outstanding matters remain in connection with this application, the Examiner is invited to telephone the undersigned at (412) 263-4340 to discuss such matters.

Respectfully submitted,



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